

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

NIPPON SHINYAKU CO., LTD., Plaintiff,	)	
v.	)	C.A. No. 21-1015 (JLH)
SAREPTA THERAPEUTICS, INC., Defendant.	)	<b>DEMAND FOR JURY TRIAL</b>
SAREPTA THERAPEUTICS, INC. and THE UNIVERSITY OF WESTERN AUSTRALIA, Defendant/Counter-Plaintiffs,	)	<div style="background-color: black; width: 100%; height: 1.2em;"></div>
v.	)	<div style="background-color: black; width: 100%; height: 1.2em;"></div>
NIPPON SHINYAKU CO., LTD. and NS PHARMA, INC., Plaintiff/Counter Defendants.	)	<div style="background-color: black; width: 100%; height: 1.2em;"></div>

**NIPPON SHINYAKU CO., LTD. AND NS PHARMA, INC.’S LETTER BRIEF  
REGARDING LATE PRODUCED LICENSING AND NO LOST PROFITS**

Judge Hall:

Nippon Shinyaku Co. Ltd. and NS Pharma, Inc. (“NS”) respectfully request that the Court (i) find that Sarepta Therapeutics, Inc. (“ST Inc.”) suffered no injury-in-fact and cannot seek or recover lost profits for the period of [REDACTED]; and (ii) grant sanctions under Rule 37(c)(1) in connection with the late-produced evidence, including precluding Counter-Plaintiffs from relying on newly-offered evidence through which Sarepta seeks to fill the gap in damages.

## I. BACKGROUND

ST Inc. sells its infringing exon 53-skipping product VYONDYS 53 (golodirsen) in the U.S. D.I. 536-2, ¶ 71. [REDACTED] Ex. A. Neither UWA nor Sarepta Therapeutics International Holdings Two, Inc. (“ST Holdings Two”) have sold any such product in the U.S. *See id.*

UWA owns the rights to the ’851 Patent asserted against NS. D.I. 536-2. As depicted in Ex. B at 1, on November 24, 2008, UWA entered an Exclusive License Agreement with AVI BioPharma, Inc., an Oregon corporation. Ex. C. AVI BioPharma, Inc. later changed its name to Sarepta Therapeutics, Inc. (“ST Oregon”), Ex. D at \*90, and on April 10, 2013, UWA, ST Oregon, and Sarepta International, C.V. (“Sarepta CV”) amended and restated the UWA license such that ST Inc. and Sarepta CV together became the “Licensee.” Ex. E. ST, Inc.—the Delaware corporation that is counter-plaintiff—was merged with ST Oregon shortly after. Ex. F, at \*87. Sarepta also [REDACTED] (depicted in Ex. B at 2-4) extending into this suit:

- [REDACTED] Ex. G.
- [REDACTED] Ex. H.
- [REDACTED] Ex. I.
- [REDACTED] Ex. J.
- In July 2021, NS filed this lawsuit. D.I. 1.
- [REDACTED] Ex. K.

For purposes of this letter brief only, NS assumes that (i) [REDACTED]

; and (ii) [REDACTED]

██████████.<sup>1</sup> Even assuming these facts in ST Inc.’s favor, one result is clear: *UWA* from the period of ██████████ for the alleged infringement of Sarepta’s patents.

## II. COUNTER-PLAINTIFFS DID NOT HAVE STANDING TO RECOVER LOST PROFITS FOR THE PERIOD OF ██████████.

Counter-plaintiffs seek lost profits damages based on *ST Inc.*’s sales. Ex. M, Jarosz Op. ¶ 98. One problem: ██████████

██████████ Ex. J. ██████████ Exs. E & G. ██████████ —approximately 10 months after NS filed suit, and 5 months after ST Inc. filed counterclaims for infringement of the UWA patents—██████████

██████████ Ex. K. The result is a ██████████ period during which ST Inc.—in fact—did not have exclusive rights to the UWA patents in the United States and suffered no injury-in-fact.

Because ST Inc. did not have exclusive rights to the UWA patents ██████████, it was—at best—a bare, non-exclusive licensee during that period. Such “[a] nonexclusive license confers no constitutional standing on the licensee to bring suit or even to join a suit with the patentee because a nonexclusive licensee suffers no legal injury from infringement.” *Sicom Sys., Ltd. v. Agilent Techs., Inc.*, 427 F.3d 971, 976 (Fed. Cir. 2005); see also *WiAV Sols. LLC v. Motorola, Inc.*, 631 F.3d 1257, 1265 (Fed. Cir. 2010) (a non-exclusive or “bare” licensee “suffers no legal injury from infringement”); *Poly-Am., L.P. v. GSE Lining Tech., Inc.*, 383 F.3d 1303, 1311 (Fed. Cir. 2004) (where party did not have exclusive rights and “received only a ‘bare license,’” it “has no entitlement under the patent statutes to itself collect lost profits damages for any losses it incurred due to infringement”). And it is undisputed that UWA has not suffered any lost profits. Counter-Plaintiffs have never alleged so. See, e.g., Ex. M ¶ 98.

Nor would joining ST Holdings Two<sup>2</sup> would *not* permit Sarepta to recover lost profits for this period. See *Crown Die & Tool Co. v. Nye Tool & Mach. Works*, 261 U.S. 24, 42 (1923) (“[T]he proper plaintiff in a suit for past infringements [i]s not the present owner of the patent” as “he did not acquire the right to bring suits for prior infringements merely by the conveyance of the full title to the patent and its enjoyment.”).

██████████ *Poly-Am.*, 383 F.3d at 1311 (“the patentee needs to have been selling some item, the profits of which have been lost due to infringing sales, in order to claim damages consisting of lost profits”). And

<sup>1</sup> ST Inc. asserts these to be true. See Ex. L, Sikora Email (5/5, 9:47 PM). If Sarepta does not establish these assumptions, a longer period of lost profits would be unavailable and/or ST Inc. would have lacked Article III standing at the case’s outset—a deficiency that cannot be cured.

<sup>2</sup> Should the Court agree that ST Inc. suffered no injury-in-fact ██████████, NS would consent to ST Holdings Two’s joinder as a counter-plaintiff seeking reasonably royalty damages (upon which Sarepta’s damages expert has already opined).

throughout this litigation, Counter-Plaintiffs have not alleged—nor offered any evidence—that ST Holdings Two itself suffered lost profits or that any of ST Inc.’s profits “inexorably flow” to ST Holdings Two. *See Intuitive Surgical, Inc. v. Auris Health, Inc.*, 2021 WL 3662842, at \*3 (D. Del. Aug. 18, 2021). Thus, ST Holdings Two would only be entitled to reasonable royalty damages.

### III. Sarepta’s arguments do not cure the lost profits issue.

During a May 5 meet-and-confer, Sarepta’s counsel suggested that this [REDACTED] did not exist because [REDACTED] (Ex. J), which states the following:

Ex. J at \*82. According to Sarepta, either (1) [REDACTED] 1; or (2) [REDACTED] Neither of these options is viable.

#### A. [REDACTED]

[REDACTED] Under either New York or Delaware law,<sup>3</sup> this recital “is not determinative of the rights and obligations of parties.” *Andersen ex rel. Andersen, Weinroth & Co., L.P. v. Weinroth*, 48 A.D.3d 121, 133, 849 N.Y.S.2d 210, 219 (2007) (internal citations omitted); *see Glidepath Ltd. v. Beumer Corp.*, 2019 WL 855660, at \*16 (Del. Ch. Feb. 21, 2019) (“Generally, recitals are not a necessary part of a contract and can only be used to explain some apparent doubt. . . . If the recitals are inconsistent with the operative or granting part, the latter controls. Preamble E is a recital. It does not establish a substantive obligation.” (internal quotations and citation omitted)). [REDACTED]

Ex. J at \*82.

[REDACTED] As discussed *supra*, non-exclusive licensees generally cannot recover lost profits for patent infringement. *See WiAV*, 631 F.3d at 1265; *Poly-Am.*, 383 F.3d at 1311; *Sicom*, 427 F.3d at 976.

#### B. [REDACTED]

As to Sarepta’s second theory, [REDACTED] Under both New York and Delaware law, a condition precedent is an act or event,

<sup>3</sup> [REDACTED]

Ex. H at \*38; Ex. K at \*39; Ex. I at \*79. T [REDACTED] Regardless, both states’ law are consistent on these issues.

other than a lapse of time, that must exist or occur before a duty to perform something promised arises.<sup>4</sup> Whether a provision qualifies as a condition precedent is a question of contract interpretation for a court to decide.<sup>5</sup> A court examines whether the parties intended for a provision to act as a condition precedent by looking to the plain language of the provision.<sup>6</sup> This is because a condition precedent must be expressed in clear and unambiguous terms.<sup>7</sup>

[REDACTED] For example, there is no “unmistakable” conditional language such as “if,” “unless and until,” or “null and void.” *New York Wheel Owner LLC v. Mammoet Holding B.V.*, 481 F. Supp. 3d 216, 248 (S.D.N.Y. 2020); *Lighthouse Behav. Health Sols., LLC v. Milestone Addiction Counseling, LLC*, 2023 WL 3486671, at \*8 (Del. Ch. May 17, 2023).

#### IV. SAREPTA SHOULD BE SANCTIONED FOR ITS LATE PRODUCTION OF THESE CRITICAL LICENSES.

Not only do the late-produced license documents preclude Sarepta from recovering lost profits for a significant portion of the damages period, the late production also warrants sanctions. “If a party fails to provide information . . . as required by Rule 26(a) or (e), the party is not allowed to use that information or witness to supply evidence on a motion, at a hearing, or at trial, unless the failure was substantially justified or is harmless.” Fed. R. Civ. P. 37(c)(1). Additionally, a court may “on motion and after giving an opportunity to be heard” order payment of reasonable expenses (including attorney’s fees) caused by the failure, inform the jury of the party’s failure, and impose other appropriate sanctions, including those listed in Rule 37(b)(2)(A)(i)-(vi). *See id.*

Sarepta’s failure to timely produce the license documents is not “substantially justified” nor “harmless.” NS requested these documents on March 11, 2022. Ex. N. Sarepta responded on April 11, 2022. Ex. L, Sikora Emails (5/5, 9:47 PM). [REDACTED]

[REDACTED] *Id.* And when Sarepta eventually produced licenses *months* later, it omitted the internal licenses it finally produced last week. *Id.*; *see also* Ex. B at 4. These documents materially affect Counter-Plaintiffs’ damages claim. Their momentous appearance on the eve of trial significantly prejudices NS’s ability to prepare its case for trial. Accordingly, NS requests its (i) costs and fees associated with Sarepta’s failure to disclose, (ii) a jury instruction regarding this failure, and (iii) other sanctions (alternatively, leave to file a formal motion seeking (i)-(iii)).

NS requests that the Court preclude Sarepta from relying upon *further* documents and evidence it

<sup>4</sup> *Nature’s Plus Nordic A/S v. Nat. Organics, Inc.*, 646 F. App’x 25, 27 (2d Cir. 2016); *Nucor Coatings Corp. v. Precoat Metals Corp.*, 2023 WL 6368316, at \*11 (Del. Super. Ct. Aug. 31, 2023).

<sup>5</sup> *Travelers Cas. & Sur. Co. v. Dormitory Auth.-State of New York*, 735 F. Supp. 2d 42, 74 (S.D.N.Y. 2010); *Nucor*, 2023 WL 6368316, at \*11.

<sup>6</sup> *Kortright Cap. Partners LP v. Investcorp Inv. Advisers Ltd.*, 327 F. Supp. 3d 673, 681 (S.D.N.Y. 2018); *Nucor*, 2023 WL 6368316, at \*11.

<sup>7</sup> *Nature’s Plus*, 646 F. App’x at 27; *Grottenthaler v. SVN Med, LLC*, 2022 WL 17249642, at \*3 (Del. Super. Ct. Nov. 28, 2022).

self-servingly produced on Monday, May 6 in an attempt to fill the gaping hole in ST Inc.’s rights. *See* Ex. L, O’Quinn Email (5/6, 1:13 PM). Failure to produce these gap-filling documents during fact discovery is neither substantially justified nor harmless, and Sarepta should be precluded from relying on them or offering testimony about them at trial. *See* Fed. R. Civ. P. 37(c)(1). Exclusion of evidence is governed by the *Pennypack* factors (“PP Factors”). *Konstantopoulos v. Westvaco Corp.*, 112 F.3d 710, 719 (3d Cir. 1997) (citation omitted).

**PP Factor 1.** NS is unfairly prejudiced by Sarepta’s late-production of this attempted gap-filling evidence. Permitting Sarepta to introduce evidence in support of its damages claim months after the discovery cut-off deprives NS of its right to challenge such information and/or present any contrary evidence. Had Sarepta disclosed this information, NS could have sought discovery on the issue and properly developed its case accordingly. Now, NS has no opportunity to explore the new evidence, let alone properly defend against it at trial (or, admittedly, on this motion).

**PP Factor 2.** The prejudice cannot be cured by permitting additional fact discovery, as supplemental expert reports and depositions would be required derailing trial to the detriment of NS. Indeed, any “last-minute addition to the record would disrupt the proceedings and cause unacceptable delay.” *ePlus, Inc. v. Lawson Software, Inc.*, 700 F.3d 509, 523 (Fed. Cir. 2012). And it would be unfair for NS to have its “case preparation impacted and disrupted at this late date.” *Finch v. Hercules Inc.*, 1995 WL 785100, at \*10 (D. Del. Dec. 22, 1995). Only exclusion could cure the prejudice that NS is suffering. *Sysmex Corp. v. Beckman Coulter, Inc.*, 2022 WL 7008282, at \*3 (D. Del. Oct. 12, 2022).

**PP Factor 3.** Permitting Counter-Plaintiffs to rely upon newly-disclosed evidence would disrupt the orderly and efficient trial. At a minimum, additional discovery and supplemental expert reports would be required, requiring a prejudicial postponement. *Siemens Mobility Inc. v. Westinghouse Air Brake Techs. Corp.*, 2019 WL 9698520, at \*2 (D. Del. Jan. 2, 2019) (“Bifurcating or postponing trial would not cure this prejudice . . . and would disrupt the orderly and efficient trial of this case.”); *see BearBox LLC v. Lancium LLC*, 2022 WL 17403466, at \*3 (D. Del. Nov. 23, 2022) (“While BearBox’s offer to . . . provide a supplemental report . . . may cure some prejudice, this would undoubtedly disrupt the trial process.” (internal citation omitted)).

**PP Factor 4.** Not only did Sarepta fail to produce these documents under Rule 26(a)(1)(A)(iii), it also failed to produce these documents that fit squarely within NS’s discovery requests served [REDACTED]. Two conclusions could be drawn. At best, the delay was grossly negligent, as Sarepta had a duty to search for these documents. *Archer v. Defs., Inc.*, 2021 WL 3033347, at \*2 (D. Del. July 19, 2021). At worst, “the level of disregard of pre-trial rulings and the well-established rules governing discovery and civil practice in federal court evinces a willful failure.” *Ely v. Cabot Oil & Gas Corp.*, 2016 WL 590370, at \*10 (M.D. Pa. Feb. 12, 2016).

**Importance.** The gap filling evidence is not important because it does not show an “exclusive” license existed. Even if it were, that is “not sufficient enough to outweigh the significant and not-reasonably-curable prejudice to” NS. *Cirba Inc. v. VMware, Inc.*, 2023 WL 6799267, at \*4 (D. Del. Mar. 30, 2023). Indeed, any prejudice suffered by Sarepta from its late disclosure results from its own lack of diligence in proving its claims.

The *Pennypack* factors thus weigh in favor of excluding this gap-filling evidence.

May 7, 2024

Respectfully submitted,

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**CERTIFICATE OF SERVICE**

I, Amy Dudash, certify that on May 7, 2024, I caused a copy of NS's Letter Brief Regarding Late Produced Licensing and No Lost Profits which was filed under seal, to be served via electronic mail on the following counsel of record:

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